REMARKS/ARGUMENTS

This Amendment is submitted in response to the Office Action mailed January 9, 2008. Claims 1, 3 and 5-11 are currently pending in the application, with claims 7-11 having been previously withdrawn. By this paper, claims 1 and 6 are amended and claims 3 and 5 have been cancelled. Support for the amendments to claims 1 and 6 is found throughout the specification, including at paragraphs 21, 30 and 51, among others. Accordingly, claims 1 and 6 are presented for the Examiner's consideration.

REJECTION UNDER 35 U.S.C. §112 SECOND PARAGRAPH

In the most recent Office Action, the Examiner maintained the rejection of claim 6 as being indefinite under 35 U.S.C. §112, second paragraph. By this paper, claim 6 is amended as suggested by the Examiner. Applicants respectfully request withdrawal of this rejection in light of this amendment.

REJECTION UNDER 35 U.S.C. §112 FIRST PARAGRAPH

The Examiner next rejected claims 1, 3, 5 and 6 under 35 U.S.C. §112, first paragraph, separately for asserted insufficient written description and lack of enablement. Although the Applicants disagree with the Examiner's analysis in making these rejections and thus respectfully traverse them, by this paper, claims 1 and 6 have been amended to be directed to pharmaceutical combinations comprising Gly_2GLP-2 and exendin (9-39), and claims 3 and 5 have been cancelled in order to further prosecution in this case. Applicants reserve the right to file claims of breadth identical to those as filed in a continuation or divisional application. In light of the Examiner's affirmative statements on page 4, the amendments made herein overcome the written description rejection under 35 U.S.C. §112, first paragraph. Applicants respectfully request its withdrawal.

As to the enablement rejection under 35 U.S.C. §112, the Examiner cites the Wands factors set forth in *In re Wands* and discussed in MPEP §2164.01(a) to support the assertion that the claims are not enabled by the specification. 858 F.2d 731, 737, 8

USPQ2d 1400, 1404 (Fed. Cir. 1988). Applicant notes that only some of the Wands factors were discussed by the Examiner in the rejection, contrary to MPEP §2164.01(a), which states that "[i]t is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others. The examiner's analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole." Applicants respectfully request reconsideration of this rejection in light of the amendments made herein and in light of the overall balance of the evidence as a whole, when considered in light of each of the Wands factors.

First, applicants note that in light of the amendments made to the claims herewith, the breadth of the pending claims has been reduced, both in the pharmaceutical combinations claimed, and in their prospective uses. The invention is pharmaceutical in nature, and is supported by animal studies included and discussed in the specification. Indeed, as noted previously, in the present application, the Applicants provided the study of intracerebroventricular peptide injections on food intake in mice. Applicants assert that these first two Wands factors favor patentability of the pending claims.

The Examiner addressed the next Wands factor relating to the state of the prior art when discussing the result obtained in the Tang-Christensen et al. article. Applicants remind the Examiner of paragraph [0051] of the specification of the instant application, which addresses differential results in rat, mouse and human models. Specifically, the application expects a differential result in rats and humans and proposes solutions for addressing the issue. The art cited by the Examiner is thus overcome by the specification and its disclosure. This also supports a finding that the level of one of ordinary skill in the art (the next Wands factor) had risen from the time of publication of the Tang-Christensen article in 2000 and the filing of the present application. This data also addresses the Wands predictability factor, showing that one of ordinary skill had greater understanding of the models involved at the time of filing of the present

application, thus increasing the predictability in the art. These factors further support allowance of the claims as amended herein.

The remaining Wands factors, (a) the amount of direction provided by the inventor, (b) the existence of working examples and (c) the quantity of experimentation needed also favor the allowance of the pending claims. Specifically, in the present application, the inventors provide ample support for formulations of Gly_2GLP-2 and exendin (9-39) and provide data from mouse models as to its use and disclosure as to how to carry the effect of induced anorexia into human and other species. As noted previously, Applicants also provide teachings as to how methods and combinations according to the present invention may be adapted for use in different species, dosing considerations, and discussion of various formulation types and routes. *See, e.g.,* paragraphs [0038]-[0049]. Applicants thus submit that the claims as amended herein are supported by the specification and should be allowed.

CONCLUSION

Applicants respectfully assert(s) that claims 1 and 6 are thus allowable as amended herein, and request that a timely Notice of Allowance be issued in this case. If there are any remaining issues preventing allowance of the pending claims that may be clarified by telephone, the Examiner is requested to call the undersigned.

Respectfully submitted,

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